

SUPPORT FOR THE AMENDMENTS

Claim 1 was previously canceled.

Claim 4 has been canceled.

Claims 5, 6, 8, 9, 20 and 21 have been amended.

Claims 22-29 have been added.

Support for the amendment of Claims 5, 6, 8, and 9 is provided by the corresponding claims as originally filed and by the specification at, for example, paragraphs [0020], [0021], and [0024] on pages 5-6. The amendment to Claims 20 and 21 serves to correct a typographical error and is supported by the claims as previously presented and by, for example, paragraphs [0029]-[0036] on pages 7-9 as well as the Examples. Claims 22 and 26 find support in paragraph [0030] on pages 7-8. Claims 23 and 27 find support in paragraph [0022] on page 6. Claims 24 and 28 find support in paragraph [0023] on page 6. Claims 25 and 29 find support in paragraph [0027] on page 7.

The specification has been amended to correct a typographical error appearing in the original text of this application at page 10, line 25 where “calcium glycerophosphate” inadvertently was presented as “sodium glycerophosphate”. Support for this amendment is provided by paragraphs [0009], [0024], etc., where the second composition (B) contains calcium salt of an organic acid, such as calcium salt of glycerophosphate. Thus, composition B in the Example that Applicants seek to correct is a calcium salt. Additionally, Applicants note that all the other examples contain calcium glycerophosphate. Applicants believe that these descriptions support the fact that “sodium glycerophosphate” at page 10, line 25 is a typographical error of “calcium glycerophosphate”.

No new matter has been added by the present amendments.

REMARKS

Claims 2-29 are pending in the present application.

Applicants wish to thank Examiner Sutton and Examiner Fetterolf for the helpful and courteous discussion with their undersigned Representative on December 17, 2008. During this discussion, various amendments and arguments (including those presented herein) were discussed. The content of this discussion is believed to be accurately reflected by the amendments and comments presented herein. Reconsideration of the outstanding rejections is requested in view of the amendments and remarks herein.

The rejections of:

- (a) Claims 2-7, 9, and 12-15 under 35 U.S.C. §103(a) over Winston et al (US 5,858,333) in view of Tomlinson et al (US 4,048,300);
- (b) Claims 14-17 and 21 under 35 U.S.C. §103(a) over Winston et al (US 5,858,333) in view of Tomlinson et al (US 4,048,300) and further in view of Grabenstetter et al (US 4,083,955);
- (c) Claims 8, 10, 11, 18, and 19 under 35 U.S.C. §103(a) over Winston et al (US 5,858,333) in view of Tomlinson et al (US 4,048,300) and further in view of Wiesel (US 6,287,120); and
- (d) Claim 20 under 35 U.S.C. §103(a) over Winston et al (US 5,858,333) in view of Tomlinson et al (US 4,048,300) and further in view of Wiesel (US 6,287,120) and Grabenstetter et al (US 4,083,955)

are respectfully traversed.

As previously established in the response filed on July 15, 2008, Winston et al fail to disclose or suggest alternately applying a first composition (A) and a second composition (B) to a tooth where the first composition (A) contains a fluoride ion-supplying compound and an inorganic phosphoric acid or a salt thereof; and the second composition (B) contains a calcium salt of organic acid, wherein an organic acid constituting the calcium salt of organic acid has a pKa value ranging from 3 to 11, or at least one pKa value ranging from 3 to 11 when the organic acid has plural pKa values.

Winston et al disclose one-part or two-part products for remineralizing or mineralizing teeth (see Abstract). However, throughout the specification, Winston et al disclose that “when the product... is ready to be used, the cationic and anionic components are mixed together with water and/or saliva to form the mixed aqueous composition... The anionic and cationic components are mixed only when the components are introduced into the oral cavity or immediately before their introduction into the oral cavity” (see page 23, line 29 to page 24, line 6). Further, at page 36, lines 11-29, Winston et al specifically disclose “When using the two-part aqueous products of this invention, the time period between the mixing of the first and second parts and the application of the resulting mixed aqueous composition to the teeth should not exceed 1 minute.... An important feature of the present invention lies in the mixing of the anionic and cationic components and the quick and timely application of the resulting mixed composition to the tooth...”

In view of the foregoing and the remainder of the disclosure by Winston et al, including the Examples, it is clear that the two-part system disclosed therein is either mixed simultaneously (at best in the oral cavity as opposed to on the tooth surface) or pre-mixed before application to the oral cavity or teeth. In contrast, the claimed invention requires the alternate application of composition (A) and composition (B). The meaning of “alternate

application” is clear from the disclosure of the present application and means that either composition (A) or composition (B) is applied to the teeth followed after a certain time interval the application of the other composition (see, for example, paragraphs [0011], [0019], and [0032]-[0034], and the Examples). Winston et al does not disclose or suggest the alternate application as claimed.

The foregoing distinction is important for two reasons. First, the fact that Winston et al does not disclose or suggest the alternate application as claimed means that this reference cannot anticipate the claimed invention. Second, Applicants submit that the claimed method provides a substantial unexpected advantage with respect to fluorine uptake as compared to either simultaneously applying (A) and (B) or pre-mixing (A) and (B) prior to application, each of which is more representative of the disclosure of Winston et al.

In the Office Action mailed October 31, 2008, the Examiner acknowledged that Winston et al fails to disclose the method of alternately applying the separate compositions. In an attempt to compensate for this deficiency, the Examiner cites Tomlinson et al, which Applicants submit does not.

Winston et al disclose a two-part product containing a cationic part and an anionic part. The anionic part may contain at least one water-soluble fluoride salt. These salts are preferably present in the anionic part rather than in the cationic part so as to avoid formation of sparingly soluble calcium fluoride (see, column 8, lines 53-59). Although the cationic part may contain MFP (monofluorophosphate) with calcium salt, Winston et al specifically disclose that inclusion of MFP in the cationic part is less desirable due to the potential loss of fluoride (see, column 9, lines 17-21).

Therefore, Winston et al discloses the product which includes a cationic part containing calcium supplier and an anionic part containing sodium fluoride and MFP, while

the reference does not specifically disclose a product including fluoride in both parts or a product including both MFP and calcium salt in one part, but rather discloses that such a product would not be desirable and/or would be expected to have poor fluorine uptake properties.

Example 12 of Tomlinson et al do not include a calcium salt of polyol phosphate or organic acid. The product of Tomlinson et al also do not contain fluoride in both parts. Additionally; in the second solution of Example 12 of Tomlinson et al, calcium phosphate should be immediately precipitated and only a very small amount of calcium remains in supernatant. The specification of Tomlinson et al does not provide any further clarity with respect to the specific ingredients of the compositions making up the claimed product. And thus, fails to compensate for the deficiencies in Winston et al.

In contrast to Winston et al, the claimed two-part product includes composition (A) containing an inorganic fluoride and composition (B) containing MFP and calcium salt of polyol phosphate, which thus includes fluoride in both parts and contains both MFP and calcium salt in one part. To demonstrate the unexpected results flowing from the claimed invention as compared to the stated expectation in Winston et al, Applicants **submit herewith** a Declaration under 37 C.F.R. §1.132 executed by Mr. Atsushi Yamagishi (“the Yamagishi Declaration”).

In the Yamagishi Declaration, the declarant compared the claimed product to Example 5 of Winston, which, of the Examples, provides the highest increase in hardness (see Table VII).

As shown in Table 1 of the Yamagishi Declaration, the amount of fluorine uptake derived from the claimed product was nearly three times larger ($2.00 \mu\text{g}/\text{cm}^2$ vs. $0.75 \mu\text{g}/\text{cm}^2$) than that derived from Comparative Example B1 (Example 5 composition of US 5,858,333

(“Winston”). Comparing with the Comparative Example B2, which is the Example 5 composition of Winston further containing MFP in Part A, the claimed product resulted in more than two-fold fluorine uptake ($2.00 \mu\text{g}/\text{cm}^2$ vs. $0.82 \mu\text{g}/\text{cm}^2$). In Comparative Example B3, in which MFP was contained in Part A as the only fluorine supplier, fluorine uptake was poor (0.05). (see paragraph 6 of the Yamagishi Declaration)

On the basis of these data, the declarant of the Yamagishi Declaration states:

Winston disclose that the cationic part (i.e., Part A) may contain MFP (monofluorophosphate) with calcium salt, but it is less desirable due to the potential loss of fluoride (see, column 9, lines 17-21). As a result, Winston does not provide any Examples in which MFP is used. Thus, based on the disclosure of Winston, the artisan would have expected that the presence of MFP in the cationic part (i.e., Part A) would result in the loss of fluoride and would be dissuaded from using MFP in this part. Indeed, as illustrated in Comparative Example B2 above, adding MFP to part A of Example 5 of Winston resulted in poor fluorine uptake.

In contrast to the expectation presented by the disclosure of Winston, the claimed product, which includes MFP with calcium salt (i.e., in Part A), leads to excellent fluoride uptake rather than resulting in loss of fluoride (see, Table 1 above). Such excellent fluoride uptake (i.e., two-fold over Winston’s composition with MFP in Part A and nearly three-fold of Winston’s exemplified composition) provided by the claimed invention is in no way expected from the disclosure of Winston.

This result is also unexpected even when considering the disclosures of US 4,048,300 (Tomlinson), US 4,083,955 (Grabenstetter), and/or US 6,287,120 (Wiesel). (see paragraph 8 of the Yamagishi Declaration)

The Examiner is reminded that “[a] prima facie case of obviousness ... is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties.” See MPEP §2144.09 (citing *In re Paesch*, 315 F.2d 381 (C.C.P.A. 1963)). Applicants submit that the results summarized above and provided in the Yamagishi Declaration establish that the claimed dental product possesses unexpected advantages and superior properties as compared to the products disclosed in Winston et al., even when viewed with Tomlinson et al..

The Examiner is further reminded of the fact that Winston et al fail to disclose the alternate application of the two compositions of the presently claimed invention. The advantages of the same were demonstrated in the Declaration under 37 C.F.R. §1.132 submitted on July 15, 2008 (“the July 15, 2008 Declaration”). In the July 15, 2008 Declaration, Applicants showed the following comparison of the results obtained as a measure of fluorine uptake ($\mu\text{g}/\text{cm}^2$) for the claimed method and two methods that are representative of the disclosure of Winston et al:

	Alternately applying (A) and (B) ⁱ		Simultaneously applying (A) and (B) ⁱⁱ		Pre-mixing (A) and (B) ⁱⁱⁱ	
	1 min.	3 min.	1 min.	3 min.	1 min.	3 min.
Example 1	5.2	13.5	0.3	0.4	0.1	0.2
Example 2	5.8	15.8	0.6	0.6	0.2	0.2
Example 3	4.9	11.5	0.8	0.9	0.3	0.4
Example 4	0.6	5.2	0.2	0.2	0.1	0.1
Example 5	0.3	3.8	0.1	0.1	0.1	0.1

i) Alternately applying (A) and (B): alternately at 10 second intervals

ii) Simultaneously applying (A) and (B): mixed at teeth

iii) Pre-mixing (A) and (B): pre-mixed for 10 seconds prior to application to teeth

These results clearly evidence the unexpected superiority of the claimed method with respect to fluorine uptake is demonstrated as compared to method representing the disclosure of Winston et al, even when viewed with Tomlinson et al, which further rebuts the alleged obviousness rejection.

Grabenstetter et al and Wiesel fail to compensate for the deficiencies above in the combined disclosures of Winston et al and Tomlinson et al. Specifically, Grabenstetter et al

also does not disclose the product containing fluoride in both parts. Wiesel is only cited for referring to carrier, but offers nothing with respect to the aforementioned deficiencies.

In view of the foregoing, Applicants respectfully request that these grounds of rejection be withdrawn.

The objection to Claims 20 and 21 as being drawn to a “production” as opposed to a “product” is obviated by amendment. Applicants have made to appropriate amendment herein. Withdrawal of this ground of objection is requested.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)